



01-07-05

IFW

Application No.: 10/615,213

Docket No.: 01946/100G906-US2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
William E. BAY et al.

Application No.: 10/615,213

Confirmation No.: 8060

Filed: July 7, 2003

Art Unit: 1625

For: DISODIUM SALTS, MONOHYDRATES, AND
ETHANOL SOLVATES FOR DELIVERING
ACTIVE AGENTS

Examiner: Paul J. KILLOS

REQUEST FOR WITHDRAWAL OF NOTICE OF ABANDONMENT

MAIL STOP PETITION
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants in the above-identified patent application have received a NOTICE OF ABANDONMENT, mailed December 29, 2004 (copy enclosed as Exhibit A), advising that the application has been abandoned due to applicants' alleged failure to timely respond to an Office Action mailed June 23, 2004. The last day to timely file a Response to this Office Action was December 23, 2004 (with a three-month extension of time).

The Patent Office is respectfully advised that on December 23, 2004, Applicants submitted pursuant to 37 C.F.R. § 1.10, *inter alia*, an Amendment in Response to a Non-Final Office Action, a Three Month Request Extension of Time under 37 C.F.R. § 1.136(a), and Check No. 7124 for \$1,020 to cover the three month extension of time fee. In support thereof Applicants enclose the following:

(a) A copy of the originally-deposited postcard listing, *inter alia*: "Amendment in Response to Non-Final Office Action"; "Three Month Request for Extension of Time Under 37

C.F.R. § 1.136(a)"; and "Check No. 7124 for \$1020.00"; showing the number of the "Express Mail" mailing label thereon (EV 382054156) (Exhibit B);

(b) A copy of the Amendment In Response to Non-Final Office Action, a Petition for a Three Month Extension of Time under 37 C.F.R. § 1.136(a), and a Certificate of Express Mailing under 37 C.F.R. § 1.110, as timely filed on December 23, 2004 (Exhibit C);

(c) A copy of the "Express Mail" mailing label showing the "date-in," on the "Express Mail" mailing label (December 23, 2004) entered by the U.S. Postal Service. (Exhibit D);

(d) A "Track & Confirm" Report from the U.S. Postal Service, indicating that Express Mail Package EV 382054156 was delivered at 8:31 a.m. on December 27, 2004 to Patent Office, Alexandria, VA 22313, and signed for by M. Boston (Exhibit E);

(f) A declaration signed by Bruce W. Lee, docketing clerk at Darby & Darby P.C., describing the procedure followed by our Docketing Department in the handling of mail to the Patent Office (Exhibit F).

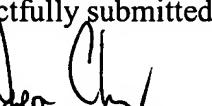
Applicants note that a return post-card has not yet been received by Applicant's counsel. The copies of the correspondence (Exhibits B and C), the "Express Mail" mailing label (Exhibit D), and the official notation entered by the USPS (Exhibit D) are true copies of the originally mailed correspondence, original "Express Mail" mailing label, and official notation entered by the USPS.

We contacted our bank, Citibank, N.A., to determine if Check No. 7124 in the amount of \$1020.00 has cleared. According to Citibank records, there is no indication that Check No. 7124 has cleared, although we understand that it usually takes about two weeks for such records to be updated. Applicants do not submit a second check herewith, since it is believed that Check No. 7124 is in the PTO awaiting processing (or has already been processed). If any additional fees are due, the Commissioner is hereby authorized to charge them to deposit account No. 04-0100.

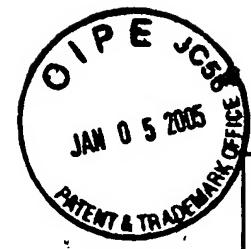
For these reasons, applicants respectfully submit that the Notice of Abandonment was erroneously mailed, and request its withdrawal.

Dated: January 5, 2005

Respectfully submitted,

By 
Jason C. Chumney

Registration No.: 54,781
DARBY & DARBY P.C.
P.O. Box 5257
New York, New York 10150-5257
(212) 527-7700
(212) 753-6237 (Fax)
Attorneys/Agents For Applicant



Application No. (if known): 10/615,213

Attorney Docket No.: 01946/100G906-US2

Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. [REDACTED] in an envelope addressed to:

EV382053969-US

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on January 5, 2005
Date

Signature

Typed or printed name of person signing Certificate

Registration Number, if applicable

Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Request for Withdrawal of Notice of Abandonment (3 pages)
Exhibits A-F (19 pages)
Fee Transmittal (1 page)
Return Postcard

JAN 05 2005

PATENT & TRADEMARK OFFICE

Under the Paperwork Reduction Act of 1995, no person are required to respond to a collection of information unless it displays a valid OMB control number.

Effective on 12/08/2004.

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL

For FY 2005

 Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 0.00)

Complete if Known

Application Number	10/615,213
Filing Date	July 7, 2003
First Named Inventor	Moise Azria
Examiner Name	P. J. Killos
Art Unit	1625
Attorney Docket No.	01946/100G906-US2

METHOD OF PAYMENT (check all that apply)

Check Credit Card Money Order None Other (please identify): _____

Deposit Account Deposit Account Number: 04-0100 Deposit Account Name: Darby & Darby P.C.

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

Charge fee(s) indicated below Charge fee(s) indicated below, except for the filing fee

Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17 Credit any overpayments

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description

Each claim over 20 (including Reissues)

Fee (\$)	Small Entity Fee (\$)
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50 25

Each independent claim over 3 (including Reissues)

200 100

Multiple dependent claims

360 180

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	Multiple Dependent Claims	Fee (\$)	Fee Paid (\$)
- 28 =	x	=				
Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)			
- 4 =	x	=				

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
- 100 =	/50	(round up to a whole number) x	=	

4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): _____

SUBMITTED BY		Registration No. (Attorney/Agent)	Telephone
Signature	<i>jlcm</i>	54,781	(212) 527-7700
Name (Print/Type)	Jason C. Chumney	Date	January 5, 2005

Express Mail Label No. _____ Dated: _____



UNITED STATES PATENT AND TRADEMARK OFFICE

*Taylor Chumney
D1946/1G906-US2*

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,213	07/07/2003	William E. Bay	1946/1G906-US2	8060

7590 12/29/2004

DARBY & DARBY P.C.
805 Third Avenue
New York, NY 10022

EXAMINER

KILLOS, PAUL J

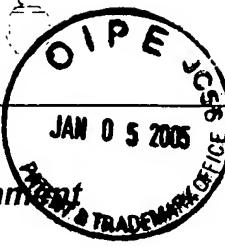
ART UNIT

PAPER NUMBER

DUE: PETITION To Re vive
Docketed on 1/3 by DP for DATE MAILED: 12/29/2004
Docketed without file
Attorney _____

Please find below and/or attached an Office communication concerning this application or proceeding.





Notice of Abandonment

Application No.

10/615,213

Examiner

Paul J. Killos

Applicant(s)

BAY ET AL.

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. Applicant's failure to timely file a proper reply to the Office letter mailed on 23 June 2004.
 - (a) A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
 - (b) A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.
(A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
 - (c) A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
 - (d) No reply has been received.

2. Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
 - (a) The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
 - (b) The submitted fee of \$_____ is insufficient. A balance of \$_____ is due.
The issue fee required by 37 CFR 1.18 is \$_____. The publication fee, if required by 37 CFR 1.18(d), is \$_____.
 - (c) The issue fee and publication fee, if applicable, has not been received.

3. Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
 - (a) Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
 - (b) No corrected drawings have been received.

4. The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.

5. The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.

6. The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.

7. The reason(s) below:

Paul J. Killos
Primary Examiner
Art Unit: 1625

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.



Atty Docket No.: 01946/100G906-US2

Applicant: William E. Bay et al.

Appln: 10/615,213 Filed: Jul. 7, 2003

Title: DISODIUM SALTS, MONOHYDRATES, AND
ETHANOL SOLVATES FOR DELIVERING ACTIVE
AGENTS

Documents:

Fee Transmittal for FY 2005 (1 page);

Three Month Request for Extension of Time Under
37 CFR 1.136(a) (1 page);

Amendment in Response to Non-Final Office Action (8 pages);

Amendment Transmittal Letter (1 page)

Certificate of Express Mailing (1 page); and

Check No. 7124 for \$1,020.00

Ev 382054156-us

Via: Express Mail: Airbill No.

Sender Initials: JCC/sjw Date: December 23, 2004

J.W. Lee

DARBY & DARBY, P.C. PATENT OFFICE ACCOUNT 805 THIRD AVENUE NEW YORK, NY 10022		1-8-210	7124
PAY TO THE ORDER OF	COMMISSIONER OF PATENTS & TRADEMARKS	DATE	12/23/04
<u>One Thousand Twenty</u>		\$ 1020.00	X
citibank*		DOLLARS	XX
CITIBANK, N.A. BR.#852 153 EAST 53RD STREET NEW YORK, NY 10043		The Citigroup Private Bank	
MEMO 615,213 /100G906US2 +0210000891: 43348071W 7124		Gabriella V. Kacsozi	



Application No. (if known): 10/615,213

Attorney Docket No.: 01946/100G906-US2

Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. _____ in an envelope addressed to:

Commissioner for Patents **EJ 382054156 - US**
P.O. Box 1450
Alexandria, VA 22313-1450

on December 23, 2004
Date

B.W. Lee

Signature

B.W. LEE

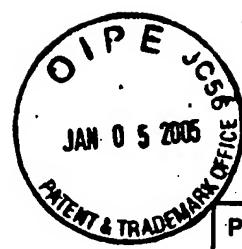
Typed or printed name of person signing Certificate

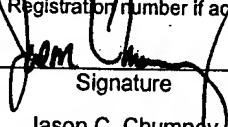
Registration Number, if applicable

Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Fee Transmittal for FY 2005 (1 page);
Three Month Request for Extension of Time Under
37 CFR 1.136(a) (1 page);
Amendment In Response to Non-Final Office Action (8 pages);
Amendment Transmittal Letter (1 page)
Return Postcard; and
Check No. 724 for \$1,020.00



PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) FY 2005 (fees effective on or after October 1, 2004)		Docket Number (Optional) 01946/100G906-US2
Application Number	10/615,213	Filed July 7, 2003
For	DISODIUM SALTS, MONOHYDRATES, AND ETHANOL SOLVATES FOR DELIVERING ACTIVE AGENTS	
Art Unit	1625	Examiner Paul J. Killos
This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.		
The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):		
	Fee	Small Entity Fee
<input type="checkbox"/> One month (37 CFR 1.17(a)(1))	\$110.00	\$55.00
<input type="checkbox"/> Two months (37 CFR 1.17(a)(2))	\$430.00	\$215.00
<input checked="" type="checkbox"/> Three months (37 CFR 1.17(a)(3))	\$1,020.00	\$510.00
<input type="checkbox"/> Four months (37 CFR 1.17(a)(4))	\$1,530.00	\$765.00
<input type="checkbox"/> Five months (37 CFR 1.17(a)(5))	\$2,080.00	\$1,040.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. <input checked="" type="checkbox"/> A check in the amount of the fee is enclosed. <input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached. <input type="checkbox"/> The Director has already been authorized to charge fees in this application to a Deposit Account. <input checked="" type="checkbox"/> The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number <u>04-0100</u> . I have enclosed a duplicate copy of this sheet.		
I am the	<input type="checkbox"/> applicant/inventor. <input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96). <input type="checkbox"/> attorney or agent of record. Registration Number _____ <input checked="" type="checkbox"/> attorney or agent under 37 CFR 1.34(a). Registration number if acting under 37 CFR 1.34(a) <u>54,781</u>	
 <u>Jason C. Chumney</u> Typed or printed name		Date <u>December 23, 2004</u> Telephone Number <u>(212) 527-7700</u>
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.		
<input type="checkbox"/>	Total of <u>1</u>	forms are submitted.

Express Mail Label No.

Dated:



AMENDMENT TRANSMITTAL LETTER

Docket No.
01946/100G906-US2

Application No.
10/615,213

Filing Date
July 7, 2003

Examiner
Paul J. KILLOS

Art Unit
1625

Applicant(s): William E. Bay et al.

Invention: DISODIUM SALTS, MONOHYDRATES, AND ETHANOL SOLVATES FOR DELIVERING ACTIVE AGENTS

TO THE COMMISSIONER FOR PATENTS

Transmitted herewith is an amendment in the above-identified application.

The fee has been calculated and is transmitted as shown below.

CLAIMS AS AMENDED

	Claims Remaining After Amendment	Highest Number Previously Paid	Number Extra Claims Present	Rate	
Total Claims	28	- 28 =		x	0.00
Independent Claims	4	- 4 =		x	0.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					
Other fee (please specify): Extension for response within 3 RD month					1,020.00
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT:					1,020.00

Large Entity

Small Entity

No additional fee is required for this amendment.

Please charge Deposit Account No. _____ in the amount of \$ _____.

A check in the amount of \$ 1,020.00 to cover the filing fee is enclosed.

Payment by credit card. Form PTO-2038 is attached.

The Director is hereby authorized to charge and credit Deposit Account No. 04-0100 as described below. A duplicate copy of this sheet is enclosed.

Credit any overpayment.

Charge any additional filing or application processing fees required under 37 CFR 1.16 and 1.17.

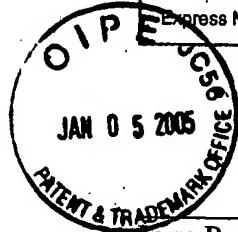
Dated: December 23, 2004

Jason C. Chumney
Attorney Reg. No.: 54,781

DARBY & DARBY P.C.
P.O. Box 5257
New York, New York 10150-5257
(212) 527-7770

Express Mail Label No. _____

Dated: _____



Express Mail Label No.

Dated: _____

Docket No.: 01946/100G906-US2
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
William E. Bay et al.

Application No.: 10/615,213

Confirmation No.: 8060

Filed: July 7, 2003

Art Unit: 1625

For: DISODIUM SALTS, MONOHYDRATES, AND
ETHANOL SOLVATES FOR DELIVERING
ACTIVE AGENTS

Examiner: Paul J. Killos

AMENDMENT IN RESPONSE TO NON-FINAL OFFICE ACTION

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INTRODUCTORY COMMENTS

In response to the Office Action mailed June 23, 2004, please amend the above-identified U.S. patent application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

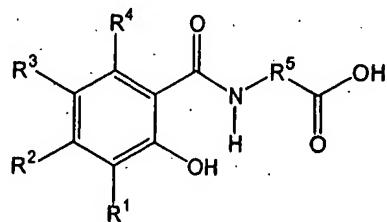
Remarks begin on page 7 of this paper.

This submission is accompanied by a request for a three-month extension of time.

AMENDMENTS TO THE CLAIMS

Please amend the claims so that they read as follows:

1. (Original): A disodium salt of a delivery agent having the formula



wherein

R¹, R², R³, and R⁴ are independently hydrogen, -OH, -NR⁶R⁷, halogen, C₁-C₄ alkyl, or C₁-C₄ alkoxy;

R⁵ is a substituted or unsubstituted C₂-C₁₆ alkylene, substituted or unsubstituted C₂-C₁₆ alkenylene, substituted or unsubstituted C₁-C₁₂ alkyl(arylene), or substituted or unsubstituted aryl(C₁-C₁₂ alkylene); and

R⁶ and R⁷ are independently hydrogen, oxygen, or C₁-C₄ alkyl.

2. (Original): The disodium salt of claim 1, wherein the delivery agent is *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid.

3. (Original): The disodium salt of claim 1, wherein the delivery agent is *N*-(10-[2-hydroxybenzoyl]amino)decanoic acid.

4. (Original): The disodium salt of claim 1, wherein the delivery agent is sodium *N*-(8-[2-hydroxybenzoyl]amino)caprylic acid.

5. (Original): An ethanol solvate of the disodium salt of claim 1.

6. (Original): The ethanol solvate of claim 5, wherein the delivery agent is *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid.

7. (Original): The ethanol solvate of claim 5, wherein the delivery agent is *N*-(10-[2-hydroxybenzoyl]amino)decanoic acid.

8. (Original): The ethanol solvate of claim 5, wherein the delivery agent is sodium *N*-(8-[2-hydroxybenzoyl]amino)caprylic acid.

9. (Original): A monohydrate of the disodium salt of claim 1.

10. (Original): The monohydrate of claim 9, wherein the delivery agent is *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid.

11. (Original): The monohydrate of claim 9, wherein the delivery agent is *N*-(10-[2-hydroxybenzoyl]amino)decanoic acid.

12. (Original): The monohydrate of claim 9, wherein the delivery agent is sodium *N*-(8-[2-hydroxybenzoyl]amino)caprylic acid.

13. (Original): A composition comprising at least about 50% by weight of the disodium salt of claim 1, based upon 100% total weight of delivery agent and salts thereof in the composition.

14. (Original): The composition of claim 13, wherein the composition comprises at least about 90% by weight of the disodium salt, based upon 100% total weight of delivery agent and salts thereof in the composition.

15. (Original): A composition comprising:

(a) the disodium salt of claim 1, ethanol solvate thereof, or monohydrate thereof; and

(b) at least one active agent.

16. (Original): The composition of claim 15, wherein the composition comprises at least about 50% by weight of the disodium salt, based upon 100% total weight of delivery agent and salts thereof in the composition.

17. (Original): The composition of claim 16, wherein the composition comprises at least about 90% by weight of the disodium salt, based upon 100% total weight of delivery agent and salts thereof in the composition.

18. (Original): The composition of claim 15, wherein the composition comprises at least about 90% by weight of the monohydrate, based upon 100% total weight of hydrate of the disodium salt of the delivery agent in the composition.

19. (Original): The composition of claim 15, wherein the active agent is selected from the group consisting of growth hormones; human growth hormones; recombinant human growth hormones; bovine growth hormones; porcine growth hormones; growth hormone-releasing hormones; interferons; α -interferon; β -interferon; γ -interferon; interleukin-1; interleukin-2; insulin; porcine insulin; bovine insulin; human insulin; human recombinant insulin; insulin-like growth factor; IGF-1; heparin; unfractionated heparin; heparinoids; dermatans; chondroitins; low molecular weight heparin; very low molecular weight heparin; ultra low molecular weight heparin; calcitonin; salmon calcitonin; eel calcitonin; human calcitonin; porcine calcitonin; erythropoietin; atrial natriuretic factor; antigens; monoclonal antibodies; somatostatin; protease inhibitors; adrenocorticotropin; gonadotropin releasing hormone; oxytocin; leutinizing-hormone-releasing-hormone; follicle stimulating hormone; glucocerebrosidase; thrombopoietin; filgrastim; prostaglandins; cyclosporin; vasopressin; cromolyn sodium;

sodium chromoglycate; disodium chromoglycate; vancomycin; desferrioxamine; parathyroid hormone; fragments of parathyroid hormone; antimicrobials; anti-fungal agents; vitamins; analogs, fragments, mimetics and polyethylene glycol-modified derivatives of these compounds; and any combination thereof.

20. (Original): The composition of claim 15, wherein the active agent is selected from the group consisting of heparin and calcitonin.

21. (Original): A dosage unit form comprising:

- (a) the composition of claim 15; and
- (b) (i) an excipient,
- (ii) a diluent,
- (iii) a disintegrant,
- (iv) a lubricant,
- (v) a plasticizer,
- (vi) a colorant,
- (vii) a dosing vehicle, or
- (viii) any combination thereof.

22. (Original): A solid dosage unit form comprising a lyophilized mixture comprising

- (a) the disodium salt of claim 1; and
- (b) at least one active agent.

Claims 23-28 (Canceled)

29. (New): A method for administering salmon calcitonin to an animal in need thereof, the method comprising administering orally to the animal a composition comprising:

- (a) N-(5-chlorosalicyloyl)-8-aminocaprylic acid, wherein N-(5-chlorosalicyloyl)-8-aminocaprylic acid comprises at least about 96% by weight of the disodium salt of N-(5-chlorosalicyloyl)-8-aminocaprylic acid; and
- (b) salmon calcitonin.

REMARKS**Status of the Claims**

Claims 23-28 have been canceled without prejudice or disclaimer. Claim 29 has been added, support for which can be found, for example, on page 8, lines 16-23; and page 5, lines 8-12.

As amended the claims are drawn to two inventions: (1) claims 1-22 are drawn to disodium salts of delivery agents, including ethanol solvates and monohydrates thereof, and compositions and unit dosage forms containing the same; and (2) claim 29 is drawn to a method for administering salmon calcitonin.

Rejections Under 35 U.S.C. §102

Claims 1, 2, 4, 5, 7-9 and 11-28 stand rejected as anticipated by WO 96/30036. The Examiner contends that disodium salts are formed in situ when the compounds are treated with sodium hydroxide. Disodium salts are not explicitly disclosed or suggested in WO 96/30036. The claimed compounds have two ionizable sites, one at the carboxyl terminus and one at the 2-hydroxy group on the phenyl ring. Treatment with the amount of sodium hydroxide specified in WO 96/30036 will not form the disodium salt because of the extremely low reaction constant (K_a) of the 2-hydroxy group. Therefore WO 96/30036 does not anticipate claims 1, 2, 4, 5, 7-9 and 11-28. Accordingly applicants request withdrawal of this rejection.

In view of the above remarks, applicant believes the pending application is in condition for allowance.

Dated: December 23, 2004

Respectfully submitted,

By Jason C. Chumney
Jason C. Chumney

Registration No.: 54,781
DARBY & DARBY P.C.
P.O. Box 5257
New York, New York 10150-5257
(212) 527-7700
(212) 753-6237 (Fax)
Attorneys/Agents For Applicant



Customer Copy

Label 11-F June 2002

EXPRESS



EV 382054121 US

ORIGIN (POSTAL USE ONLY)

PO ZIP Code 10022	Day of Delivery 23	Flat Rate Envelope <input checked="" type="checkbox"/>
Date In 12/23/04	Next Day <input type="checkbox"/>	Second Day <input checked="" type="checkbox"/> 12/27/04
Mo. Day 12	12 Noon <input checked="" type="checkbox"/>	3 PM <input type="checkbox"/>
Time In 6:00	Military <input type="checkbox"/>	Return Receipt Fee <input type="checkbox"/>
AM <input type="checkbox"/>	PM <input checked="" type="checkbox"/>	2nd Day <input type="checkbox"/>
Weight 10.3	3rd Day <input type="checkbox"/>	10th Alpha Country Code <input type="checkbox"/>
Ins. <input type="checkbox"/>	Acceptable <input checked="" type="checkbox"/>	COD Fee <input type="checkbox"/>
No Delivery <input type="checkbox"/>	Initials CS	Total Postage & Fees \$ 7.85
Weekend <input type="checkbox"/>	Holiday <input type="checkbox"/>	Insurance Fees <input type="checkbox"/>

CUSTOMER USE ONLY
METHOD OF PAYMENT:
Business Mail Corporate Acc. No.

FROM: (PLEASE PRINT)

DARBY & DARBY PC
805 3RD AVE FL 21
NEW YORK

TO: (PLEASE PRINT)

MAIL STOP
COMMISSIONER FOR PATENTS
PO BOX 1450
ALEXANDRIA
VA 22313-1450

Box: Response 2

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Track & Confirm

Current Status

You entered EV38 2054 156U S

Your item was delivered at 8:31 am on December 27, 2004 in ALEXANDRIA, VA 22313 to PATENT OFFICE. The item was signed for by M BOSTON.

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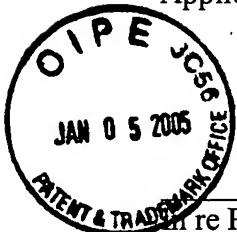
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
William E. BAY et al.

Application No.: 10/615,213

Confirmation No.: 8060

Filed: July 7, 2003

Art Unit: 1625

For: DISODIUM SALTS, MONOHYDRATES, AND
ETHANOL SOLVATES FOR DELIVERING
ACTIVE AGENTS

Examiner: Paul J. KILLOS

DECLARATION OF BRUCE W. LEE

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Bruce W. Lee, declare as follows:

1. I am employed as a Docketing Clerk at Darby & Darby, P.C. I make this declaration in support of the accompanying REQUEST FOR WITHDRAWAL OF NOTICE OF ABANDONMENT, which seeks the withdrawal of the NOTICE OF ABANDONMENT mailed on December 29, 2004, in the above-identified application.

2. A true copy of the Notice of Abandonment mailed December 29, 2004 is attached as Exhibit A. The Notice of Abandonment states that the applicant failed to timely file a proper reply to the Office Action mailed on June 23, 2004, and that no reply has been received.

3. A true copy of the Amendment In Response to Non-Final Office Action submitted on December 23, 2004 is attached as Exhibit C. Exhibit C also includes a Petition for a Three Month

Extension of Time, and an executed Certificate of Express Mailing Under 37 CFR 1.10 dated December 23, 2004, which includes my signature.

4. In accordance with our office procedure, the secretary of the attorney who prepared the papers being transmitted to the U.S. Patent and Trademark Office ("USPTO") would have brought the papers to the docketing department. The docketing department would have reviewed the papers for completeness and, if satisfied, would have imprinted, signed, and dated the Express Mail Certificate. The docketing department would then have placed it in a properly addressed postage paid envelope for mailing to the USPTO. Incomplete or unsigned papers would not be placed in the envelope, but would be returned to the attorney. At the end of the day, the docketing department forwards the USPTO envelope to our services department to be mailed with the U.S. Postal Service (USPS).

5. Attached as Exhibit B is a true copy of a self addressed postcard stamped with Express Mail tracking number EV 382054156 and a true copy of a check for \$1020.00. These items would have accompanied the other papers, and I would have considered the papers incomplete in their absence.

6. Attached as Exhibit D is a true copy of an Express Mail label which lists the same tracking number, EV 382054156, as stamped on the self-addressed postcard (Exhibit B). This Express Mail label has a USPS mailroom stamp dated December 23, 2004. This confirms that the originals of Exhibits B and C were mailed on that date.

7. The return, stamped postcard has not yet been received by applicant's counsel.

8. Based upon the presence of the Certificate of Express Mailing I signed, the postcard I signed, and the USPS-stamped Express Mail receipt, it may be concluded that the originals of Exhibits B and C were timely filed on December 23, 2004, in accordance with normal procedures at Darby & Darby.

All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the

knowledge that willful and false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: January 5, 2005

Respectfully submitted,

By Bruce W. Lee
Bruce W. Lee
Docketing Clerk
DARBY & DARBY P.C.
P.O. Box 5257
New York, New York 10150-5257
(212) 527-7700
(212) 753-6237 (Fax)